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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,053	05/10/2001	Stephan Berens	P 280248 000091 BT	3782
909	7590	12/01/2004	EXAMINER	
PILLSBURY WINTHROP, LLP			FRONDA, CHRISTIAN L	
P.O. BOX 10500			ART UNIT	
MCLEAN, VA 22102			PAPER NUMBER	

1652

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/852,053

Applicant(s)

BERENS ET AL.

Examiner

Christian L Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20 and 24-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24-29, 31 and 40-43 is/are allowed.
- 6) ☒ Claim(s) 20, 30 and 32-39 is/are rejected.
- 7) ☒ Claim(s) 32-34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. In the **AMENDMENT AND RESPONSE PURSUANT TO 37 C.F.R. § 1.111** dated 08/16/2004, applicants have canceled claims 21-23; amended claims 20 and 27-30; and added new claims 41-43.
2. Claims 20 and 24-43 are under consideration in this Office Action.
3. The rejection of claims 27-29 and 31-39 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of Applicants' claim amendments.
4. The rejection of claims 21, 30, and 32 under 35 U.S.C. 103(a) is moot and has been withdrawn in view of applicants' cancellation of claim 21 and amendment of claims 30 and 32.

Claim Objections

5. Claims 32-34 are objected to because of the following informalities: claims 32-34 depend in the alternative to canceled claims 21-23. Appropriate correct is required such that the claims are rewritten to depend from currently pending claims 20, 24, or 27.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. Claims 20, 30, and 32-39 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 3, an isolated polynucleotide encoding a

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polypeptide comprising the amino acid sequence of SEQ ID NO: 4, a vector comprising said polynucleotide, and a recombinant *Corynebacterium glutamicum* comprising said polynucleotide; does not reasonably provide enablement for any other embodiment.

Applicants' arguments filed 08/16/2004 have been fully considered but they are not persuasive. Applicants' position is that due to the teachings of the specification one of skill in the art would not require undue experimentation to identify specific catalytic amino acids and structural motifs essential for the enhanced export of amylase by the SecD and SecF proteins having 90% amino acid sequence identity to SEQ ID NO:3 and SEQ ID NO: 4, respectively. The Examiner respectfully disagrees for reason of record as supplemented below.

SEQ ID NO: 3 is disclosed as consisting of 637 amino acids and SEQ ID NO: 4 is disclosed as consisting of 403 amino acids. Thus, the claims encompass polynucleotides encoding polypeptides with amino acid sequences that have 573 amino acid residues that are identical to SEQ ID NO: 3 and up to 64 amino acid residues that are different (substitutions, deletions, or insertions with any amino acid residue) from SEQ ID NO: 3 since the claim recites the limitation of 90% identity to SEQ ID NO: 3. Furthermore, the claims also encompass polynucleotides encoding polypeptides with amino acid sequences that have 363 amino acid residues that are identical to SEQ ID NO: 4 and up to 40 amino acid residues that are different (substitutions, deletions, or insertions with any amino acid residue) from SEQ ID NO: 4 since the claim recites the limitation of 90% identity to SEQ ID NO: 4.

Neither the specification nor the general knowledge of those skilled in the art provide guidance or prediction regarding the specific 64 or 40 amino acid residues in SEQ ID NO: 3 or 4 which can be changed without inactivating the secretion activity of the claimed polypeptides of SEQ ID NO: 3 or 4. The specification does not provide working examples for selecting the specific 64 or 40 amino acid residues in SEQ ID NO: 3 or 4 to change without inactivating the secretion activity.

Since neither the specification nor information known in the art provide guidance or prediction for the specific amino acid residues that can be changed without inactivating amylase secretion activity, one must perform an enormous amount of trial and error experimentation to determine which 64 or 40 amino acid residues in SEQ ID NO: 3 or 4 can be changed in a polypeptide to make a polypeptide that has an amino acid sequence that is at least 90% identical to SEQ ID NO: 3 or 4, respectively, and yet has amylase secretion activity. Such trial and error experimentation is well outside the realm of routine experimentation and entails selecting any 64 or 40 amino acid residues in SEQ ID NO: 3 or 4 to modify, searching and screening for the type of modification to perform on the selected amino acid residues (deletion, insertion, substitution, additions or combinations thereof) which will not result in a loss of amylase secretion activity, determining whether the variant polypeptide has any amylase secretion activity, and then making the corresponding polynucleotides that encode the variant polypeptide. Teaching regarding screening and searching for the claimed invention using assays stated in the specification is not

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guidance for making the claimed invention.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the amino acid residues which can be changed without inactivating amylase secretion activity. Without such a guidance, the amount of experimentation left to those skilled in the art to make the claimed invention is undue and well outside of routine experimentation. Claims 30, and 32-39 which depend from claim 20 stand rejected because they do not correct the defect of claim 20.

Conclusion

8. Claims 24-29, 31, and 40-43 are allowed.

9. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). CLF

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A handwritten signature in black ink, appearing to read "Manjunath N. Rao" with a stylized flourish at the end.

Manjunath N. Rao
Primary Examiner
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